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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.		
09/981,123	10/16/2001	James L. Holloway	99-88C1	6433		
7590 01/15/2004			EXAMINER			
Phillip B.C. Jones, J.D., Ph.D.			FRONDA, CHRISTIAN L			
ZymoGenetics, Patent Departm		ART UNIT	PAPER NUMBER			
1201 Eastlake Avenue East			1652			
Seattle, WA 9	8102		DATE MAILED: 01/15/2004	DATE MAILED: 01/15/2004		

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary			Application No.		Applicant(s)				
			09/981,123		HOLLOWAY, JAMES L.				
			Examiner		Art Unit				
			Christian L F	ronda	1652	L.,			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period f r Reply									
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).									
Status		_							
·	Responsive to communication(s) filed or		=	<i>a.</i> .					
′=	,		action is non						
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.									
Dispositio	n of Claims								
4) 🗌 C	Claim(s) is/are pending in the application.								
4:	4a) Of the above claim(s) is/are withdrawn from consideration.								
5)⊠ C	5) Claim(s) 1 and 20-22 is/are allowed.								
6)□ (	6) Claim(s) is/are rejected.								
7) 🗌 C	Claim(s) is/are objected to.								
8) <u> </u>	8) Claim(s) are subject to restriction and/or election requirement.								
Applicatio	n Papers								
9)☐ The specification is objected to by the Examiner.									
10) $\boxtimes$ The drawing(s) filed on <u>16 October 2001</u> is/are: a) $\boxtimes$ accepted or b) $\square$ objected to by the Examiner.									
A	applicant may not request that any objection	to the dr	Irawing(s) be	held in abeyance. See	37 CFR 1.85(a).				
F	Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).								
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.									
Priority under 35 U.S.C. §§ 119 and 120									
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:									
<ul> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> </ul>									
	3. Copies of the certified copies of the priority documents have been received in this National Stage								
application from the International Bureau (PCT Rule 17.2(a)).									
* See the attached detailed Office action for a list of the certified copies not received.									
13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.									
a) The translation of the foreign language provisional application has been received.									
14)⊠ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.									
Attachment(s	· s)		•						
	of References Cited (PTO-892)			Interview Summary (					
	of Draftsperson's Patent Drawing Review (PTO-9 ation Disclosure Statement(s) (PTO-1449) Paper			Notice of Informal Pa	tent Application (PTC	)-152)			
ınıorma نے رہ	auon Disclosure Statement(s) (210-1449) Paper	NU(\$)	6	Other: .					

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### **DETAILED ACTION**

#### Election/Restriction

- 1. Applicants' election of Group I, claims 1-6 and 20, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The restriction requirement is deemed proper for reasons of record and is therefore made FINAL.
- 2. Applicants' cancellation of claims 2-19, amendment of claims 1 and 20, and addition of claims 21 and 22 is acknowledged.
- 3. Claims 1 and 20-22 are under consideration in this Office Action.

## Claim Rejections - 35 U.S.C. § 101

- 4. 35 U.S.C. 101 reads as follows:

  Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.
- 5. Claims 1 and 20-22 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well established utility.

Applicants disclose the nucleotide sequence of SEQ ID NO: 1, the deduced amino acid sequence of the protein encoded as SEQ ID NO: 2, and assigned the protein of SEQ ID NO: 2 as a human serine protease which is a generic asserted utility. Serine protease are known in the prior art as a large group of enzymes with different structures and biological functions. However, the specification does not disclose the **specific** function of the protein of SEQ ID NO: 2 and any activity assays to demonstrate that the protein serine protease activity.

Substantial utility is one that provides a specific benefit in currently available form at the time of filing of the invention. However, the main utility of the nucleic acid and protein is to carry out further research to identify the biological function associated with the protein. Utilities that require or constitute carrying out further research to identify or reasonably confirm a specific use are not substantial utility and do not provide a specific benefit. Thus, the claimed invention has no specific or substantial asserted utility.

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## Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

- 6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

  The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- 7. Claims 1 and 20-22 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above in the rejection of claims 1 and 20-22 under 35 U.S.C. 101, one skilled in the art clearly would not know how to use the claimed invention.

## Conclusion

- 8. No claim is allowed.
- 9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. The fax phone number for this Group is (703)308-0294. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

**CLF** 

PONNATHAPU ACHUTAMURTHY SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 1600